

REMARKS

Claims 21-33 were the subject of the Office Action dated December 22, 2008.

New Claims 34 and 35 are added. Basis for these claims can be found in paragraphs 21 and 22 of the published application US 20050181058, in the three Examples, and in original claims 21, 22, and 24, for example.

Claim 22 is combined into Claim 21. As such, Claim 22 is cancelled without prejudice.

Claims 27, 30, 31, and 33 are cancelled without prejudice in favor of the remaining claims. This should render moot the indefiniteness rejection.

Accordingly, Claims 21, 23-26, 28, 29, 32, and 34-35 are now presented for further consideration.

Claims 21-33 stand rejected as lacking adequate written description under 35 USC §112, first paragraph. The applicant respectfully traverses this rejection.

The applicant understands the examiner to be saying that the terms unsubstituted polysaccharides, galactomannans, and glucomannans are all too broad and are not adequately supported by the specification.

First, all of the claims now refer to galactomannans and/or glucomannans. The applicant submits that this is a reasonable genus.

Page 4 of the Final Office Action dated December 22, 2008, states "the disclosure specifies only a single polysaccharide which is guar." This is untrue, as Example 2 of the subject application also discloses the use of konjac flour, and Example 3 also discloses the use of potato starch. Guar gum is a galactomannan; galactomannans are polysaccharides consisting of a mannose backbone with galactose side groups. Galactomannans are well-known in the art, and the fact that the term exists and is used in the art should be evidence of that. The same is true for glucomannans. Konjac flour consists mainly of glucomannan, which is composed of glucose and mannose subunits. Starch is a polysaccharide of glucose monosaccharide units.

As such, the applicant submits that the specification demonstrates that the full scope of the claimed invention was more than adequately possessed. Thus, this rejection should be rendered moot.

In light of the foregoing, the withdrawal of this rejection under 35 USC § 112, first paragraph, is respectfully requested.

Claims 27, 30, 31, and 33, stand rejected under 35 USC § 112, second paragraph, as being indefinite. This rejection is rendered moot by the cancelation of these claims.

Claims 21-33 stand rejected under 35 USC §103(a) as being obvious over GB 2257358. Applicant respectfully traverses this rejection.

The active substances in the cited reference are mixed prior to being embedded in the polysaccharide matrix. The embedding process described in the cited reference is designed to protect the active substances from pressure and temperature during industrial processes.

In contrast, the subject claims of the present application specify that the first active substance and the second active substance are, in a first step, separately embedded within separate polysaccharide matrices. As specified in independent Claim 21, the process of solely embedding the first active substance and the second active substance, in separate polysaccharide matrices, results in the first granule particle having embedded only the first active substance and the second granule particle having embedded only the second active substance. The first active substance, solely embedded in first granule particles, and the second active substance, solely embedded in second granule particles, are then administered to the human or animal as a plurality of granule particles.

As disclosed in the subject application, embedding the first active substance within a polysaccharide matrix, separate from the second active substance, allows for a time-controlled release of the active substances and prevents the active substances from reacting or interacting with each other (for example, during manufacture, when in packaging, or after consumption). Furthermore, the subject invention allows for the creation of individual compositions or preparations, such as individual dosages, consisting of specific amounts of the first and second active substances, for example.

It is clear that GB 2257358 teaches mixing of the active substances prior to mixture with the polysaccharide (unlike what is advantageously claimed according to embodiments of the

subject invention). For example, the following Examples of GB 2257358 read as follows:

Example 2 states, "Enzymes or enzyme mixtures are mixed into...flour and sprayed..."

Example 3 states, "...enzymes or enzyme mixtures are embedded in a polysaccharide... Enzymes or enzyme mixtures are mixed into...flour and sprayed into a mixer together..."

Example 4 states, "Enzymes or enzyme mixtures are incorporated in oil and emulsified with...flour solution in the emulsifier and sprayed into fine guar flour with mixing..."

Example 6 states, "Enzymes or enzyme mixtures are homogenised in guar endosperm flour in a mixer."

Example 7 states, "...flour is mixed in the mixer with the calculated amounts of coenzyme powder and enzyme powder protected by embedding in nonionic polysaccharides... [from] ...Heat and pressure applications ..."

Example 8 states that it is similar to Example 7 but that "flours are used in conjunction with proteins and nutrient fibres and combined with, for example, vegetable, fruit, meat, and fish powder."

It is clear that there is no prevention of interaction being addressed or even suggested by the cited reference. The only problem being addressed is inactivation of enzymes and the like during industrial processing. Hence, mixing of active ingredients prior to processing with polysaccharides was perfectly acceptable according to the cited reference. The active ingredients are mixed in the first step and are then embedded in a second step. The differences in the manufacturing processes and the implications for the subsequent uses, as claimed, were simply not in, or apparent from, the art.

Thus, the subject invention as claimed offers several advantages that were not even contemplated by the cited art. For example, the subject invention can prevent the separate active substances from reacting within the body of the individual too early, because they are separately embedded in a polysaccharide-matrix. In addition, another advantage is that the separate active substances are prevented from reacting or interacting with each other during manufacture or storage (after manufacture) because they are separately embedded in a polysaccharide-matrix - solely and separated from the other active substances. Still further, yet another advantage is that the subject invention makes it easily possible to obtain an individual composition or preparation, i.e. individual dosage, for any individual.

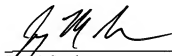
Thus, the cited reference does not disclose, teach, or provide motivation for the claimed process. In addition, the cited art is totally silent regarding possible advantages, which are thus clearly surprising, offered by the subject invention – including those of having the first active substance is embedded in a polysaccharide matrix separate from the second active substance. As such, and in light of the foregoing, the withdrawal of this obviousness rejection is respectfully requested.

In the event Applicant has overlooked the need for an extension of time, payment of fee, or additional payment of fee, Applicant hereby petitions therefor and authorizes that any charges be made to Deposit Account No. 02-0385, Baker & Daniels LLP.

Should the Examiner have any questions regarding any of the above, the Examiner is respectfully requested to telephone the undersigned at 317-237-1245.

Respectfully submitted,

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